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LAHTIVE AND COCKFIELD  
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BOSTON MA 02109

EXAMINER

PORTNER, V

ART UNIT

PAPER NUMBER

1641

19

DATE MAILED:

12/14/95

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

## OFFICE ACTION SUMMARY

- Responsive to communication(s) filed on 7-23-98 + 11-5-98 + 9-8-98.
- This action is FINAL.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

- Claim(s) 13, 93-109, 139-141 (now claims 10-12) is/are pending in the application.
- Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- Claim(s) \_\_\_\_\_ is/are allowed.
- Claim(s) \_\_\_\_\_ is/are rejected.
- Claim(s) \_\_\_\_\_ is/are objected to.
- Claims 13, 93-109, 110-112 are subject to restriction or election requirement.

## Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- All  Some\*  None of the CERTIFIED copies of the priority documents have been received.
- received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- Notice of Reference Cited, PTO-892
- Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- Interview Summary, PTO-413
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Notice of Informal Patent Application, PTO-152

- SEE OFFICE ACTION ON THE FOLLOWING PAGES -

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**DETAILED ACTION**

Claims 13, 93-109 and 139-141 (which were renumbered as claims 110-112) are pending in the instant Application.

1. **Telephone Interview Summary and Election/Restriction Bonafide Attempt**

In a telephone interview with Ms Amy Mandragouras and Ms Linda Chinn, on November 19, 1998, the Preliminary Amendment dated December 18, 1995 (page number 5) which submitted new claims and canceled others was discussed; a duplicate copy of this amendment, along with a copy of the return postcard was received on November 23, 1998 and entered into the case on November 25, 1998. This Amendment had been made of record on the file face but was not entered into the case. This preliminary Amendment was not considered by the examiner at the time of the original Election/Restriction requirement. The original Election/Restriction requirement dated January 21, 1998, on paper number 13, only considered the claims as originally filed with the case on June 7, 1995, specifically claims 1-6.

Applicant's written election, dated July 23, 1998 has been made of record; the cancellation and entry of new claims was carried out upon receipt of the duplicate copy of the Preliminary Amendment submitted in 1995.

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In light of the forgoing events the response to the Election/Restriction requirement, of paper number 13, dated July 23, 1998 has been considered to be a bonafide attempt to the election restriction requirement set forth in the last office action.

The supplemental Amendment faxed into the US PTO on November 5, 1998, submitting claims 94-95 and claims 139-141 will be entered, as the Amendment was signed by Applicant, but the claims will be renumbered in light of Rule 1.126 to be in numerical sequence with the claims now pending.

***Election/Restriction***

The election/restriction requirement made of record is herewith withdrawn, in light of the now pending claims.

2.     Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I.     Claim 103 is drawn to various proteins, classified in class 530, subclass 350.
  - II.    Claims 13, 93-102 and 110-112 are, drawn to isolated nucleic acid molecules, classified in class 536, subclass 23.1.
  - III.   Claims 107-109 are drawn to a method of screening compounds for their ability to bind polypeptides, classified in class 424, subclass 9.2.
  - IV.    Claims 104-106, drawn to methods of treating a subject for infection, classified in class 530, subclass 387.1.

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3. The inventions are distinct, each from the other because of the following reasons:
4. The invention of group I is distinct from the invention of group II because it is drawn to materially different compositions that require non-coextensive areas of search and consideration. For example, the proteins of the invention of Group I may be isolated from natural sources and are not necessarily defined by the DNAs that encode them.
5. The inventions of groups I and III are distinct, one from the other, because they are drawn to materially different proteins with distinct structural and chemical properties. Specifically, the binding compounds of group III, which encompasses antibodies, as well as other compounds, requires search and consideration of the preparation of the protein binding agent and at a structural level, antibodies are distinct from the proteins that they may bind.
6. Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product , specifically in methods of detecting antibodies, in methods of purifying antibodies, as well as in methods of generating a vaccine .

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7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their different classification, recognized divergent subject matter, and because the searches required for the separate groups of inventions are non-coextensive, restriction for examination purposes as indicated is proper.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Claim 103 is to a plurality of disclosed patentably distinct products comprising materially different proteins. Should the inventions of Group I be elected, Applicant would be required under 35 U.S.C. 121 to elect a single disclosed product, even though this requirement is traversed. The separate proteins bear no structural or biochemical property in common and therefore each particular protein product claimed and would require a separate area of search and consideration tailored to the particular product under consideration.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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In addition to the preceding restriction requirement, upon the election of Group II, the following additional election would be required:

10. Claims 13, 93-102 and 110-112 are drawn to isolated nucleic acid molecules that contain more than ten individual, independent and distinct nucleotide sequences in alternative form. Accordingly, this claim is subject to restriction under 35 U.S.C. 121 as outlined in 1192 O.G. 68 (Nov. 19, 1996).

Applicant is required to select **no more than ten of the individual polynucleotide sequences** for examination. The search of no more than ten selected sequences may include the complements of the selected sequences and, where appropriate, may include sequences within the selected sequences (e.g. oligomeric probes and/or primers), the recitation of an isolated polynucleotide sequence encoded by a polypeptide SEQ ID NO XXX would afford Applicant the opportunity to elect a single nucleotide sequence as patentability would rest upon the structure and function of the polypeptide as well as the nucleic acid sequence which encodes it. Therefore, an isolated nucleic acid molecule of SEQ ID NO XXX which encodes a polypeptide, would define patentably distinct sequences not covered by the election/restriction rules for expressed sequence tags (EST); claims which recite multiple amino acid sequences which are encoded by an isolated nucleic acid molecule would be considered by the examiner as an improper Markush group as each polypeptide would evidence patentably distinct structural and functional characteristics and the mere association of the molecules because of origin does not provide for the establishment of a proper Markush group claim. Election of a single nucleic acid sequence

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which in codes a polypeptide would be required if the claims were to recite claim limitations which would not qualify the claim as an EST claim.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be changing February 7, 1998. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art 1641.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp  
November 25, 1998

*James C. Housel*  
JAMES C. HOUSEL 12/6/98  
SUPERVISORY PATENT EXAMINER